Supreme Court, U.S.
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In The

Supreme Court of the United States

October Term, 1997

HOWMEDICA, INC., a Division of Pfizer Hospital Products Group, Inc.,

Petitioner,

vs.

GEORGE E. ELBERT,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

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48 pp

QUESTION PRESENTED

Whether the Ninth Circuit erred by holding, in direct conflict with opinions of the Third Circuit, that a district court considering a post-verdict motion for judgment must give weight to expert testimony deemed unreliable on appeal.

PARTIES TO THE PROCEEDING

Petitioner Howmedica Inc. is a wholly-owned subsidiary of Pfizer Inc.

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PETITION FOR WRIT OF CERTIORARI

Petitioner Howmedica Inc. prays that a writ of certiorari issue to review the judgment and opinion of the Ninth Circuit entered in this proceeding on May 8, 1998, in order to resolve a direct conflict with the Third Circuit on the question of whether evidence improperly admitted at trial should be considered upon a post-verdict motion for judgment under Rule 50(b) of the Federal Rules of Civil Procedure. This case presents an excellent opportunity for exercise of this Court's certiorari jurisdiction, because review would resolve a clear split between the circuits. The split will not resolve on its own, because the Third Circuit has repeatedly and emphatically rejected the reasoning espoused by the Ninth Circuit, and the Ninth Circuit has acknowledged but failed to address the Third Circuit's criticism. If allowed to stand, the Ninth Circuit's decision will greatly increase the caseload and administrative expenses of the federal courts, because it mandates a new trial in all cases where evidence is held inadmissible after verdict or on appeal. The Ninth Circuit's adoption of a blanket rule poses a particular threat to the vitality of this Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993), because it gives a party whose witness was struck under *Daubert* the right to name a new expert in an area already held lacking in scientific validity.

OPINIONS BELOW

The decision of the Ninth Circuit Court of Appeals in *Elbert v. Howmedica, Inc., a Division of Pfizer Hospital Products Group, Inc.*, CV-91-00616 BMK, is reported at 143 F.3d 1208 (9th Cir. 1998) (Appendix "App." 1). The judgment of the District Court for the District of Hawaii which was the subject of this appeal (App. 7) is not reported. The prior decision of the Ninth Circuit Court of Appeals in this case reversing the judgment in favor of plaintiff (App. 22) is not reported. 59 F.3d 174 (table) (9th Cir. 1995).

STATEMENT OF JURISDICTION

The judgment of the Ninth Circuit Court of Appeals was filed and entered May 8, 1998. The jurisdiction of this Court is timely invoked under 28 U.S.C. § 1254(1).

STATEMENT OF THE CASE

A. The First Trial

Respondent filed this product liability suit, involving a Porous Coated Anatomic Primary Knee prosthesis manufactured by Petitioner ("P.C.A. Knee"), in the state court in Hawaii in October 1991. Petitioner removed the suit to the United States District Court for the District of Hawaii on October 31, 1991.

During the pretrial phase of the case, several rulings were issued limiting Respondent's ability to present expert testimony. In mid-March, 1993, Petitioner took the

depositions of the two experts identified by Respondent. One, Kenneth Kayser, was an electrical engineer who had no prior experience with prosthetic knees or with the ultra-high molecular weight polyethylene that had allegedly failed in Respondent's P.C.A. Knee. On the basis of several articles, some of which had been furnished to him by Respondent's attorney, he stated opinions both as to Petitioner's standard of care and as to proximate causation. The other expert, Curtis Watts, an aeronautical engineer, also had no prior experience with prosthetic knees or with ultra-high molecular weight polyethylene. Mr. Watts, however, was not prepared to state any opinions as of the time of his deposition. On March 31, 1993, almost four months after his deadline for naming experts, Respondent belatedly identified eight new expert witnesses. Petitioner brought an expedited discovery motion to strike the new experts and to limit the testimony of Messrs. Kayser and Watts and for sanctions as to the unprepared Mr. Watts. Following a hearing, the Court entered an order on May 24, 1993 stating that: "The new witnesses may not be called by plaintiff as expert witnesses and may not testify on issues of liability and/or causation in this case." As to the unprepared expert, Respondent was ordered to fly Mr. Watts to Honolulu and to pay all costs for three hours of additional deposition time. These rulings were not challenged on appeal.

Trial in the case commenced August 3, 1993. Respondent proceeded on the theory that a proprietary heat-pressing method used by Petitioner in the manufacture of the ultra-high molecular weight polyethylene tibial insert of the P.C.A. Knee had caused Respondent's tibial insert

to delaminate. The only expert Respondent offered at trial on the issues of standard of care and causation was Kenneth Kayser, who, as stated, had no training on or familiarity with the manufacture or use of prosthetic knee joints or the polyethylene component at issue. The trial court denied Petitioner's motion to exclude Mr. Kayser's testimony. Mr. Kayser testified that Howmedica had failed to adhere to reasonable manufacturing practices and that its negligence had caused Respondent's injury.

Petitioner moved for judgment as a matter of law at the close of Respondent's case, arguing that Mr. Kayser's testimony was not reliable or entitled to weight and that, as a consequence, Respondent had failed to satisfy its evidentiary burden. The court, acknowledging that the question of Mr. Kayser's expert testimony was a "close one," denied the motion. The jury returned a verdict for Respondent on the counts of negligence and breach of warranty and for Petitioner on the strict product liability claim. After the verdict was entered, Petitioner renewed its motion for judgment as a matter of law. The court denied Petitioner's post trial motion, noting that the evidence was sufficient based upon Mr. Kayser's testimony. Petitioner appealed.

B. The First Appeal

In June 1995, the Ninth Circuit reversed the judgment in favor of Respondent on the grounds that Mr. Kayser should not have been deemed qualified to testify. App. 22. The Ninth Circuit found that Mr. Kayser had "presented no evidence on his experience or qualifications regarding the specific subject areas in which he offered

testimony." App. 24. The court noted that Mr. Kayser's testimony was essential to Respondent's case, since "Kayser was the only witness who offered testimony asserting that Howmedica could have known and should have known its P.C.A. Knee would delaminate and thereby produce Elbert's injury." App. 24. The court found, moreover, that "[t]he jury's award against Howmedica for negligence and breach of warranty, despite its finding of no strict liability, is strong evidence that the testimony was prejudicial." The Ninth Circuit did not order a new trial, but remanded for proceedings consistent with its opinion.

C. Proceedings on Remand

Following remand of the case, the parties filed cross-motions based on their differing views of "proceedings consistent with" the Ninth Circuit's decision. Petitioner moved for entry of judgment in its favor, arguing that Respondent's evidence was insufficient without Mr. Kayser to establish the elements of standard of care and causation. Respondent moved for a new trial, urging that he had enough evidence to sustain a verdict even without Mr. Kayser's testimony. Respondent urged that the testimony of his remaining experts would suffice, and that no expert testimony was necessary to establish his cause of action in any event. He did not argue that he should be permitted to call an additional expert witness to replace Mr. Kayser's testimony and did not indicate that he intended to retain a new expert if a new trial were granted.

After hearing, the trial court granted judgment for Petitioner. App. 7. The court considered the testimony of

each of Respondent's remaining witnesses and found that none rendered testimony on standard of care or causation. The trial court found that "absent Kayser's testimony, there was insufficient evidence of negligence or breach of implied warranty by Howmedica to support the jury verdict in favor of Respondent." App. 20.

D. The Second Appeal

By published opinion, a different panel of the Ninth Circuit (Reinhardt, Leavy and Thomas), reversed the trial court and remanded for further proceedings. App. 1. The basis for the court's decision was a theory that Respondent had not urged at trial or on appeal: that a trial court considering the sufficiency of the evidence on a post-appeal motion for judgment had to consider evidence which, like Mr. Kayser's testimony, had been improperly submitted to the jury. App. 3. The panel applied the recent decision in *Schudel v. General Electric Co.*, 120 F.3d 991, 995 (9th Cir. 1997), *cert. denied*, 118 S. Ct. 1560 (1998),[1] which held that, in considering the sufficiency of evidence on a Rule 50(b) motion, the trial court must give weight even to evidence that had been admitted in error under *Daubert*.

The panel determined that weight must be given to Kayser's improper testimony because the plaintiff had relied on the trial court's initial finding of admissibility in presenting his case.

> This rule promotes certainty: litigants need not supplement conditionally admitted evidence,

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[1] Petitioner in *Schudel* did not seek certiorari on this issue.

> perhaps, unnecessarily; and district courts need not speculate as to what other evidence might have been offered if the evidence had been excluded at trial. The rule promotes fairness: punishing a litigant for the court's erroneous admission of evidence is unfair; and the remedy of a new trial is available to both sides on equal footing.

App. 3 (quoting *Schudel*). The panel did not consider whether Respondent would or could have furnished an expert to replace Mr. Kayser if his testimony had been excluded during trial, nor did its holding give the trial court any discretion to do so. The panel concluded that it was error to deny Respondent's new trial motion since Petitioner's Rule 50(b) motion following remand should have been denied.

REASONS FOR GRANTING THE WRIT

I. THIS CASE PRESENTS AN ISSUE AS TO WHICH CIRCUIT COURTS ARE IN DIRECT CONFLICT.

There is a conflict among the Circuit Courts of Appeal on the question presented in this case. In *Aloe Coal Co. v. Clark Equipment Co.*, 816 F.2d 110 (3d Cir.), *cert. denied*, 484 U.S. 853, 108 S. Ct. 156, 98 L. Ed. 2d 111 (1987), and *Lightening Lube, Inc. v. Witco Corp.*, 4 F.3d 1153 (3d Cir. 1993), the United States Court of Appeals for the Third Circuit emphatically rejected the reasoning adopted by the Ninth Circuit in *Schudel* and the case below. If the Third Circuit's analysis had been controlling in this case, the trial court's entry of judgment would have been sustained on appeal.

The decisions below and in *Schudel* expand upon a 1973 decision from the Eighth Circuit Court of Appeals, *Midcontinent Broadcasting Co. v. North Central Airlines, Inc.*, 471 F.2d 357 (8th Cir. 1973), which in turn is based on a 1964 New Mexico Supreme Court decision, *Townsend v. United States Rubber Co.*, 74 N.M. 206, 392 P.2d 404 (N.M. 1964), *overruled on other grounds, Rhein v. ADT Automotive, Inc.*, 122 N.M. 646, 930 P.2d 783 (N.M. 1996). *Midcontinent* and *Townsend* held that a trial court may not disregard improperly admitted evidence on a motion for judgment notwithstanding the verdict ("JNOV") because the proponent of the evidence relied on the court's initial finding of admissibility and would presumptively have offered better or different evidence at trial if the objection had been timely sustained. In 1983, the Fifth Circuit Court of Appeals also endorsed this view. *Sumitomo Bank v. Product Promotions, Inc.*, 717 F.2d 215, 218 (5th Cir. 1983).

In *Aloe Coal Co. v. Clark Equipment Co.*, 816 F.2d 110 (3d Cir.), *cert. denied*, 484 U.S. 853, 108 S. Ct. 156, 98 L. Ed. 2d 111 (1987), the Third Circuit Court of Appeals sharply criticized the decisions above:

> We have carefully examined the opinions from the Fifth and Eighth Circuits and New Mexico, but regrettably we find no reasoned elaboration to support their thesis. . . . The longest discussion appears in New Mexico's *Townsend* case which, upon analysis, is one conclusory statement piled on another. *Townsend*, 392 P.2d at 406. What follows is a classic case of precedential inbreeding, where decisions multiply and parrot a holding, with no court pausing, first, to identify the competing social, public, or private interests involved, then, to resolve the possible

> conflicts, and finally, to give the public reasons for the resolution.

Aloe Coal, 816 F.2d at 115 (some internal citations omitted). The Third Circuit disagreed that detrimental reliance by the party offering testimony is a sufficient reason for giving weight to inadmissible evidence after trial. "This explanation, of course, does not address either the competing reliance concerns of the defendant, or the homespun axioms that a litigant is entitled to only one bite of the apple or only three strikes at bat." *Id.* at 116.

The strong language of *Aloe Coal* was not essential to its holding, because the Third Circuit found that plaintiff had failed to allege a cognizable injury under state products liability law. In 1993, when the Third Circuit was squarely presented with the issue, it held that improperly-admitted testimony need not be considered when resolving a renewed motion for judgment. *Lightening Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1199-1200 (3d Cir. 1993).

In *Lightening Lube*, the Third Circuit reaffirmed the reasoning of *Aloe Coal*, and renewed its earlier pointed criticism of the *Midcontinent* approach. The court acknowledged that two other Circuits had joined the *Midcontinent* line since *Aloe Coal* was decided. 4 F.3d at 1199 (citing *Jackson v. Pleasant Grove Health Care Ctr.*, 980 F.2d 692 (11th Cir. 1983); and *Douglas v. Eaton Corp.*, 956 F.2d 1339 (6th Cir. 1992)). Again dismissing the *Midcontinent* approach as "precedential inbreeding," the Third Circuit repeated *Aloe Coal*'s complaint that the majority lacked a sound rationale and failed to consider the consequences of their decisions, and expressly noted that the

Supreme Court had yet to resolve the issue. 4 F.3d at 1199 & n. 26.[2]

Lightening Lube explored and rejected *Midcontinent*'s major premise that the party offering the improper testimony changes its position in reliance upon the trial court's preliminary admission: "[W]e find no reason to suppose that a litigant would hold back significant evidence at trial." 4 F.3d at 1199-1200. The court looked at the facts of the case before it and determined that no reliance had been shown:

> Indeed, Lightening Lube has not pointed to any additional evidence of the culpability of Witco's management that it withheld at trial, but would have introduced had it known that the court ultimately would rule evidence of the state of mind concerning the counterclaim to be inadmissible.

Id. Lightening Lube also cited with approval another 1993 decision in which another Third Circuit panel (Becker, Greenberg, and Weiss) held that the trial court should have discretion to choose between new trial and JNOV when evidence was struck on appeal. *Id.* at 1199 (citing *Lippay v. Cristos*, 996 F.2d 1490, 1501 (3rd Cir. 1993)).

Schudel v. General Electric Co., 120 F.3d 991 (9th Cir. 1997), *cert. denied*, 118 S. Ct. 1560 (1998), was the first case to decide the question presented after the split in the

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[2] The *Midcontinent* panel had found support for its position in a 1940 case, *Montgomery Ward & Co. v. Duncan*, 311 U.S. 243, 85 L. Ed 147 (1940), *see Midcontinent*, 471 F.2d at 357, but the Third Circuit disputed that *Montgomery Ward* had any application. 4 F.3d at 1199.

circuits arose. The Ninth Circuit noted that the Third Circuit had rejected *Midcontinent*'s central tenet of reliance. *Schudel*, 120 F.3d at 995 n. 10 (citing *Lightening Lube)*. However, *Schudel* went on to adopt *Midcontinent* on reliance grounds without even attempting to address the question *Lightening Lube* raised. *See* 120 F.3d at 995 ("If evidence is ruled inadmissible during the course of trial, the plaintiff has the opportunity to introduce new evidence. However, when that evidence is ruled inadmissible in the context of deciding a motion for JNOV, the plaintiff, having relied on the evidence already introduced, is unable to remedy the situation.") (quoting *Jackson v. Pleasant Grove Health Care Ctr.*, 980 F.2d at 696).

Schudel was the first case to apply *Midcontinent* to the testimony of an expert witness whose scientific knowledge was judged unreliable under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). After a jury verdict for plaintiffs, the trial court reconsidered its decision to admit expert testimony linking plaintiffs' neurological complaints to exposure to cleaning solvents. The Ninth Circuit affirmed that this expert testimony should have been excluded. 120 F.3d at 997. However, the panel went on to hold that the trial court must give weight to the unreliable expert opinion in ruling on defendants' Rule 50(b) motion, based on *Midcontinent*'s presumption that plaintiff could have produced better evidence if the original expert had been excluded during trial. The *Schudel* court did not consider whether the trial court's finding of unreliability under *Daubert* made it unreasonable to presume that plaintiffs would find another witness to support their case.

The decision below reaffirms this unexamined presumption of reliance in *Schudel*. The Ninth Circuit conducted no inquiry into whether Elbert would have had other expert testimony available if Mr. Kayser's opinions had been struck earlier in the proceeding.

The First, Second, Fourth, Seventh, Tenth and District of Columbia Circuits have not yet taken a position on whether evidence struck following trial must be considered on a renewed motion for judgment. In 1988, the District of Columbia Circuit actually ordered a judgment for defendant after striking the testimony of plaintiff's expert, *see Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), but apparently it did so without express consideration of the *Midcontinent* line. *Raynor v. Merrell Pharmaceuticals, Inc.*, 104 F.3d 1371, 1373 (D.C. Cir. 1997) ("the issue of whether JNOV can be granted to redress errors of admissibility was neither briefed nor discussed in *Richardson*.") (internal citations omitted). In a later case the D.C. Circuit ruled that, because *Richardson* provided no holding on the issue, the plaintiff had waived reliance on *Midcontinent* by failing to raise it at the trial court level. *Raynor*, 104 F.3d at 1373.

Petitioner respectfully submits that this Court should accept certiorari review to settle the dispute between the circuits. The split is overt and deliberate, and it will not resolve itself.

II. THIS ISSUE IS OF CONSIDERABLE IMPORTANCE IN THE POST-*DAUBERT* WORLD.

The Ninth Circuit's recognition of an absolute right to new trial in every case where evidence in support of

the verdict is adjudged inadmissible after trial or on appeal is not only the subject of a clear split that is unlikely to resolve itself without this Court's guidance, it is also wrong and will have a very costly impact in the post-*Daubert* world. This flat rule will inevitably increase the caseload of the federal courts, increase the costs of resolving disputes, and delay the resolution of claims. The problem will likely arise in many cases, because trial courts have assumed a more activist role as gatekeepers of expert opinion testimony following *Daubert*, and there will likely be many occasions when the decision to admit expert testimony is reconsidered following trial. *Daubert* made trial judges the gatekeepers, but the Ninth Circuit's approach threatens to turn them into revolving door attendants.

The per se rule ignores the fact that in many cases there will be no substitute for evidence which has been properly excluded at trial. For example, a party may be constrained by the scheduling conference order entered in the case from calling witnesses who were not previously identified. *See* Fed. R. Civ. P. 16. Likewise, a decision to exclude an expert that is premised on a substantive determination that the expert's opinions lack scientific validity under *Daubert* cannot be fixed by finding a new expert to express the same opinion. Yet *Schudel* mandates a new trial after upholding a *Daubert* exclusion, and does so without requiring any showing by plaintiffs that they will be able to produce an expert witness who can offer new opinions that overcome the trial court's original objection. To demand a new trial without an assurance of better testimony is a gross waste of judicial resources, ignores Federal Rule 16 and turns *Daubert* on

its head. *Cf. Summers v. Missouri Pac. R.R. Sys.*, 132 F.3d 599, 608 (10th Cir. 1997) (Tacha, J., dissenting) (arguing that the majority decision, which affirmed the trial court's pretrial exclusion of expert testimony for lack of scientific validity but remanded with instructions to allow plaintiff to add new expert, was inconsistent with *Daubert*'s spirit and rationale).

In place of a per se rule, the Third Circuit properly adopted a case-by-case approach giving the district court discretion to determine whether a new trial is warranted when the decision to admit evidence is reconsidered after trial. The district courts generally possess discretion to control the flow of evidence and testimony during trial and to determine whether a request to add new witnesses should be granted. *E.g., Price v. Seydel*, 961 F.2d 1470, 1474 (9th Cir. 1992). Certiorari review would provide an opportunity for this Court to recognize that this discretion extends to post-trial proceedings, and to provide guidance on how it should be exercised.

CONCLUSION

For the reasons set forth herein, Howmedica respectfully requests the petition for certiorari be granted.

Respectfully submitted,

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FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

GEORGE ELBERT, *Plaintiff-Appellant,* v. HOWMEDICA, INC., a Division of Pfizer Hospital Products Group, Inc., *Defendant-Appellee.*	No. 96-16249 D.C. No. CV-91-00616-BMK OPINION

Appeal from the United States District Court
for the District of Hawaii
Barry M. Kurren, Magistrate Judge, Presiding

Argued and Submitted
November 5, 1997 - Honolulu, Hawaii

Filed May 8, 1998

Before: Stephen Reinhardt, Edward Leavy and Sidney R. Thomas, Circuit Judges.

Per Curiam Opinion; Concurrence by Judge Reinhardt

COUNSEL

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OPINION

PER CURIAM:

George Elbert appeals from an order granting judgment as a matter of law to Howmedica, Inc., and denying his motion for a new trial. We reverse and remand.

Following a jury verdict, the district court entered judgment of $196,755 for Elbert against Howmedica for damages caused by an allegedly defective prosthetic knee manufactured by Howmedica. In the first appeal of this case, we reversed the judgment in an unpublished opinion because the district court allowed Elbert's unqualified expert to testify. On remand, Howmedica moved "for entry of judgment in its favor on all remaining claims." It cited to Rule 7, Fed. R. Civ. P., which deals with forms of motions. The magistrate judge called it a "novel motion," treated it as a motion for judgment as a matter of law pursuant to Fed. R. Civ. P. 50(b), and granted it. The court also denied Elbert's motion for a new trial, holding in relevant part that without the expert testimony the plaintiff could not establish the standard of care required of Howmedica.

The primary question presented by this appeal is whether a trial court, in deciding a Rule 50(b) motion following a remand from an appellate decision requiring exclusion of evidence, may exclude from its decision the evidence erroneously admitted at trial. We recently considered this question in an analogous context and held that when deciding a Rule 50(b) motion following trial, the trial court should not exclude such evidence. Specifically, we wrote in *Schudel v. General Elec. Co.*, 120 F.3d

991, 995 (9th Cir. 1997), *cert. denied*, 118 S. Ct. ___ (1998) that:

> We now hold that when ruling on a Rule 50(b) motion, a district court should not exclude evidence erroneously admitted at trial. The record should be taken as it existed when the trial was closed. This rule promotes certainty: litigants need not supplement conditionally admitted evidence, perhaps, unnecessarily; and district courts need not speculate as to what other evidence might have been offered if the evidence had been excluded at trial. The rule promotes fairness: punishing a litigant for the court's erroneous admission of evidence is unfair; and the remedy of a new trial is available to put both sides on an equal footing. (citation omitted).

Schudel involved the district court's exclusion of evidence during its consideration of a Rule 50(b) motion, after the court thought better of a prior ruling admitting expert testimony. However, the logic applies with equal force to a Rule 50(b) motion made following remand after an appellate ruling that expert testimony was improperly admitted.

Thus, in this case, the trial judge erred in excluding the erroneously admitted evidence when deciding Howmedica's Rule 50(b) motion after remand. Because the Rule 50(b) motion should have been denied, the trial court also erred in denying the plaintiff's motion for a new trial. Although the parties have varied opinions on what may occur in the trial court after remand, none of those issues are before us, and our consideration of those issues would be premature and based on pure conjecture as to what motions the parties might file.

REVERSED AND REMANDED.

REINHARDT, Circuit Judge, concurring in judgment.

I agree that the proper result in this case is to reverse the judgment as a matter of law and to remand for further proceedings. While the majority seems to hold that Rule 50(b) motions on remand should always be denied, I would simply say as a flat rule that litigants may not bring such motions following remand. While my approach may not differ from the majority's from a practical standpoint, I believe it would save litigants and district courts the trouble of filing and adjudicating non-cognizable motions.

Provided it makes a motion for a directed verdict at the close of evidence, a party that loses at trial may under Rule 50(b) "renew its request for judgment as a matter of law by filing a motion no later than 10 days after the entry of judgment." Fed. R. Civ. P. 50(b); *see also Collins v. City of San Diego*, 841 F.2d 337, 342 (9th Cir. 1988) (holding that "[i]f no motion for a directed verdict has been made, a motion for judgment notwithstanding the verdict has no legal effect"). The Advisory Committee Notes explain that "[a] post-trial motion for judgment [notwithstanding the verdict] may be granted only on grounds advanced in the pre-verdict motion." Fed. R. Civ. P. 50(b) advisory committee's notes to 1991 amendment; *see also Murphy v. City of Long Beach*, 914 F.2d 183, 186 (9th Cir. 1990) (same).

As our per curiam opinion makes clear, a 50(b) motion must be based on the *entire* trial record and, in ruling on the motion, the district court must base its

decision on that entire record and cannot take into account the fact that a part of the evidence may have been improperly admitted. Per Curiam Op. at 4551-52; *see also Schudel v. General Elec. Co.*, 120 F.3d 991, 995 (9th Cir. 1997), *cert. denied*, 118 S. Ct. ___ (1998). Unless the district court grants the 50(b) motion or the court of appeals holds that the losing party was entitled to prevail, the party against whom the verdict was rendered cannot obtain a judgment as a matter of law.

I believe that the plain import of this procedural scheme is that a party may not under any circumstances make a Rule 50(b) motion on remand. The reason for this conclusion is simple. As we have just explained, it is the full trial record on which a Rule 50(b) motion must be based. Nothing, therefore, is changed for purposes of such a motion when the court of appeals holds that a portion of the evidence at trial was improperly admitted. Following remand, the district court would be faced with the *identical* question that existed at the time at which, under the Federal Rules, a 50(b) motion must be made – within ten days after the entry of judgment. The losing party at trial must either make its Rule 50(b) motion shortly after the verdict or forfeit its opportunity to do so. If it has made such a motion and lost, there is no point in, or justification for, making it once again on remand. The district court has *already* ruled, and the losing party has either accepted that ruling by not appealing or the court of appeals has concluded that it is not entitled to judgment as a matter of law. If the losing party failed to make a Rule 50(b) motion within the time prescribed by the Federal Rules of Civil Procedure, it has forfeited that

right and there is no reason, let alone provision of the Federal Rules, that would allow its revival on remand.

Because I believe that the district court should not have converted Howmedica's "novel" motion into a 50(b) motion in the first place, I concur in the judgment reversing and remanding for a new trial.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

GEORGE ELBERT, Plaintiff, vs. HOWMEDICA, a Division of PFIZER HOSPITAL PRODUCTS GROUP, INC. Defendant.	CIVIL NO. 91-00616BMK (Filed Jun 24, 1996)

ORDER GRANTING DEFENDANT'S MOTION FOR DISPOSITION OF CASE FOLLOWING REMAND AND DENYING PLAINTIFF'S MOTION FOR NEW TRIAL

The court heard Plaintiff's Motion for New Trial and Defendant's Motion for Disposition of Case Following Remand on December 15, 1995. Stanford H. Masui, Esq. appeared at the hearing on behalf of Plaintiff George Elbert ("Plaintiff" or "Elbert"). Jacqueline Earle, Esq., and Margaret Jenkins Leong, Esq., appeared at the hearing on behalf of Defendant Howmedica, Inc. ("Defendant" or "Howmedica"). After reviewing the motions and the supporting and opposing memoranda, the court GRANTS Defendant's Motion for Disposition of Case Following Remand and DENIES Plaintiff's Motion for New Trial.

BACKGROUND

This is a products liability action which commenced jury trial on August 3, 1993. On August 12, 1993, the jury rendered a verdict in favor of Plaintiff on his claims for

negligence and breach of implied warranty; the jury found Plaintiff Elbert contributorily negligent in causing his injuries. Defendant Howmedica appealed this verdict to the Ninth Circuit Court of Appeals. On June 28, 1995, the Ninth Circuit rendered its decision, affirming in part and reversing in part. *See Elbert v. Howmedica*, Mem. Op. No. 94-15683 (9th Cir. June 28, 1995).

Specifically, the Ninth Circuit reversed the admission of expert testimony by Kenneth Kayser pursuant to Fed. R. Evid. 702. The court held that Kayser presented no evidence to support his qualification in the specific areas to which he testified. The court held that Kayser improperly testified to matters which were "unequivocally outside any area of expertise he might have." Mem. Op. at 3. The court also stated in dicta that Kayser's testimony was crucial to the issue of delamination of Elbert's prosthetic knee (hereinafter sometimes referred to as the "PCA knee"). *Id.* The court further stated that there was strong evidence that Kayser's testimony was prejudicial to Defendant's position in light of the jury finding negligence and breach of implied warranty, despite a finding of no strict liability. *Id.* The Ninth Circuit rejected Defendant's contention that the verdicts were irreconcilable, while allowing that such verdicts did give an indication that Kayser's testimony had a prejudicial impact.

The Ninth Circuit affirmed this court's holding that Elbert's state law claims were not preempted by the Medical Devices Amendments to the Food and Drug Administration regulations, as well as this court's refusal to modify a stipulated protective order protecting Howmedica's confidential documents. Finally, the Ninth Circuit held that the jury's verdict, finding negligent failure

to warn and breach of implied warranty despite a finding of no strict liability, was neither unreasonable nor irreconcilable. The Ninth Circuit then remanded the case for "further proceedings consistent" with these decisions. Mem. Op. at 5.

On October 30, 1995, Elbert filed a Motion for New Trial, pursuant to Fed. R. Civ. P. 59(a), (e), and 60(b). On October 31, 1995, Howmedica filed a Motion for Disposition of Case Following Remand.

STANDARD OF REVIEW

A. Plaintiff's Motion for New Trial

Rule 59 of the Federal Rules of Civil Procedure allows a court to grant a new trial "in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States. . . . " Fed. R. Civ. P. 59(a)(1). Rule 59 likewise allows for amendments of judgment. Fed. R. Civ. P. 59(e). A motion for new trial must be made no later than ten days after entry of the judgment. Fed. R. Civ. P. 59(b). A motion for a new trial or to amend judgment is committed to the sound discretion of the trial court. *See Allied Chemical Corp. v. Daiflon, Inc.*, 449 U.S. 33 (1980) (motion for a new trial); *Metromedia Co. v. Fugazy*, 983 F.2d 350 (2d Cir.) (motion for new trial), *cert. denied*, 508 U.S. 952 (1992); *McCarthy v. Manson*, 714 F.2d 234 (2d Cir. 1983) (motion to amend judgment).

Likewise, motions for relief from judgment pursuant to Fed. R. Civ. P. 60(b) are also committed to the sound discretion of the trial court. *Maraziti v. Thorpe*, 52 F.3d 252, 253 (9th Cir. 1995); *Blair v. California*, 38 F.3d 1514, 1517

(9th Cir. 1994), *cert. denied*, ___ U.S. ___, 115 S. Ct. 1698 (1995). The court may relieve a party from a final judgment when a prior judgment upon which it is based has been reversed or otherwise vacated. Fed. R. Civ. P. 60(b)(5). Such motion must be made within a "reasonable time." Fed. R. Civ. P. 60(b).

B. Defendant's Motion for Disposition Following Remand

This court will review Defendant's Motion for Disposition Following Remand according to the standard for a renewed motion for judgment as a matter of law. Fed. R. Civ. P. 50(b). A judgment as a matter of law pursuant to Rule 50 is proper only when the evidence permits only one reasonable conclusion as to the verdict. *McGonigle v. Combs*, 968 F.2d 810, 816 (9th Cir. 1992), *cert. dismissed sub nom., Casares v. Spendthrift Farm, Inc.*, 506 U.S. 948 (1992). The court must view the evidence in the light most favorable to the nonmoving party and draw all inferences in favor of that party. *Redman v. County of San Diego*, 942 F.2d 1435, 1439 (9th Cir. 1991) (en banc), *cert. denied*, 502 U.S. 1074 (1992). A directed verdict should be granted when the evidence permits only one reasonable conclusion as to the verdict. *Glover v. BIC Corp.*, 6 F.3d 1318, 1330 (9th Cir. 1993). If conflicting inferences may be drawn from the facts, the case must go to the jury. *Id.*

DISCUSSION

Plaintiff requests that this court grant a new trial arguing, without conceding, that if Kayser's testimony was prejudicial, then a new trial is required. Plaintiff also

argues that if the Ninth Circuit determined that, once Kayser's testimony was excluded, there were no facts or evidence sufficient to uphold the jury's verdict, then the Ninth Circuit itself would have disposed of the case, without remanding it to the trial court. Finally, Plaintiff appears to argue that there is sufficient evidence, despite the excluded expert testimony, to warrant a retrial on the issues of negligence and breach of implied warranty.

Howmedica argues, both in its reply to Elbert's Motion and in its own Motion for disposition of Case, that the Ninth Circuit's order of remand does not necessarily mandate a new trial. Howmedica apparently concedes that the Ninth Circuit's silence on the issue left to this court's discretion what type of proceedings are needed to reconcile the jury's verdict and the Ninth Circuit's decision striking Kayser's testimony. Howmedica argues that this court should grant a form of summary judgment, entitled "Disposition of Case Following Remand," to Howmedica based upon Plaintiff's lack of evidence presented at the first trial showing that his injuries were due to any fault or negligence on Howmedica's part; the crux of Defendant's arguments for dispostion [sic] following remand is that, absent Kayser's testimony, there remains no evidentiary basis for finding that Defendant's conduct fell below the applicable standard of care, for that standard of care cannot be established absent expert testimony; and that no finding of unmerchantability could be sustained, absent expert testimony, sufficient for the breach of implied warranty verdict.

A. Procedure Following Remand

Plaintiff contends that "it goes without saying" that the Ninth Circuit would have reversed the trial verdicts if there were no factual or evidentiary basis for them and cites to *Forged Steel Wheel Co. v. Lewellyn* for support. 251 U.S. 511 (1920). *Forged Steel* does not support Plaintiff's proposition. The holding in *Forged Steel* was that it was not error for the appellate court to reverse the trial court judgment where the appeal turned upon only matters of law. *Id.* at 515-16. In this case, the Ninth Circuit was free to review the record of the trial and could have reversed the verdicts; as Defendant correctly notes, the Ninth Circuit was equally free to explicitly order a new trial following remand, as it has done in other cases. 28 U.S.C. § 2106; *Barber v. United States,* 711 F.2d 128 (9th Cir. 1983).

The Ninth Circuit has left it to this court to review the evidentiary record and ascertain the appropriate course to take following remand.

B. Plaintiff's Motion for New Trial

This court will consider Elbert's Motion for New Trial based upon Rule 60, rather than Rule 59, due to the issue of the timeliness of Plaintiff's Motion for New Trial.[1] This court does find that Elbert brought his motion well within the "reasonable" period required for relief from a

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[1] Although this court set a motions deadline of October 31, 1995, following remand from the Ninth Circuit, it is not clear that this deadline exempts Plaintiff from the ten day deadline under Rule 59.

judgment or order under Fed. R. Civ. P. 60(b), and within the deadline for motions set by the court on July 13, 1995.

Elbert indicates that at a new trial, his negligence case would rely upon the testimony of Dr. Allen Richardson, Defendant's witnesses Stephen Cook, and expert Dr. John Lyons, as well as evidence from Howmedica Director of Polymer Technology Caspar Stark concerning the design and development of the PCA knee and particularly the role of polyethylene wear in the failure of Elbert's PCA knee. (Pl.'s Mem. in Supp. of Mot. for New Trial, at 17.) Likewise, at a new trial, Elbert indicates he would rely upon Dr. Richardson's testimony that Elbert's PCA knee did not live up to his professional expectations, literature prepared by Defendant regarding the useful life of the PCA knee, and statements from Dr. Lyons that failure of a prosthesis within three years fell short of his performance expectations for Elbert's proof of breach of warranty.

C. Defendant's Motion for Disposition of Case Following Remand

Defendant has made a novel motion, a Motion for Disposition of Case Following Remand. Defendant made its initial motion for judgment as a matter of law at the close of Plaintiff's case, which motion was granted as to Plaintiff's claim based upon express warranty and denied in all other respects. (Order Granting in Part and Denying in Part Def. Howmedica's Mot. for J. as a Matter of Law filed August 6, 1993; filed August 25, 1993.) Defendant renewed its motion at the close of all evidence, which renewed motion was likewise denied. At this juncture,

following the Ninth Circuit's ruling that it was error to permit Kayser to testify as an expert witness at trial, this court reviews anew Defendant's motion for judgment as a matter of law. Fed. R. Civ. P. 50(b).

D. Remaining Claims

i. Negligence

Dr. Richardson was Plaintiff's treating physician, the doctor who implanted the PCA knee into Elbert's leg. At trial, Dr. Richardson offered equivocal testimony on what had been the cause of the failure of Elbert's PCA knee. He testified that he could not describe the polyethylene component of the PCA knee as having delaminated. (Transcript of Proceedings (hereinafter "Tr.") 8/3/93 at 171.) Dr. Richardson did offer that he observed the PCA knee to have "destructed, fallen apart and parts of it had come off. . . . " *Id.* at 147. Defendant points out that Dr. Richardson never gave his opinion, to a reasonable medical probability, that Elbert's PCA knee was subject to delamination. (Def.'s Mem. in Opp'n to Pl.'s Mot. at 6.)

In order to render a verdict for Plaintiff upon his negligence claim, the jury was instructed that they had to judge Howmedica's conduct by the standard of care "of a reasonably prudent manufacturer of knee prostheses." (Jury Instruction No. 22.) Defendant points out, that despite Plaintiff's contention to the contrary, none of the witnesses cited by Plaintiff, other than Kayser, testified that the testing of the heat-polished materials in the PCA knee fell below the standard of care. Cook stated that the wear testing performed on the knee was appropriate and adequate. (Tr. 8/11/93 at 13-14.) Plaintiff's witness Roy

Bloebaum did not testify that the tests he performed upon retrievals of failed prostheses would have been appropriate for Howmedica's manufacturing process. Furthermore, Bloebaum testified that it was not a design defect to employ the polyethylene material used in the PCA knee. (Video Dep. of Bloebaum 7/24/93, at 67; read into Tr. 8/4/93.) The evidence adduced at trial from Dr. Lyons indicated that Howmedica was aware of some design risks, risks which were no greater than in other products available at the time; Dr. Lyons testified that Howmedica was taking measures to optimize the PCA knee by resolving competing design concerns. (Tr. 8/9/93 at 76).

Finally, testimony from Howmedica's Stark that the polyethylene components in the PCA knee contributed to its failure, as well as the Polyethylene Awareness Series indication that a thicker component was appropriate in a knee prosthesis does not establish that Howmedica's conduct fell below the relevant standard of care. Although the polyethylene component of the PCA knee may be described as the "weak link" in the device, Plaintiff's witness Bloebaum (and others) acknowledged that it was the only material that was available at the time for such purpose. (Video Dep. of Bloebaum 7/24/93, at 67; read into Tr. 8/4/93.) Furthermore, the Polyethylene Awareness Series was not available until years subsequent to implantation of the PCA knee in Elbert; it was Elbert's physician Dr. Richardson who testified that at the time of implantation of Elbert's knee, a thinner prosthetic implant would have been preferred in order to minimize

bone loss, however, henceforth he would give consideration to a thicker component in order to reduce implant wear. (Tr. 8/3/93 at 193.)

In order for Plaintiff to prevail on a theory of negligent failure to warn, the jury had to find that Defendant failed to exercise ordinary care to give warning in the face of knowledge that the user of the product would not recognize its dangerous condition. In this case where a physican [sic] selected the product to be implanted, the adequacy of warnings is measured by the warnings given to the health care provider and the "learned intermediary" doctrine applies. *See Craft v. Peebles*, 78 Haw. 287, 304-05, 893 P.2d 138, 155-156 (1995).

Assuming that Defendant had a continuing duty to warn based upon knowledge acquired several years subsequent to the implantation of Elbert's PCA knee, there was no evidence at trial that failure to provide additional warnings to Elbert's treating physician was a cause of harm to Elbert. If Dr. Richardson were aware of the risk of bone loss from synovitis, an inadequacy in Howmedica's warning in light of acquired knowledge would not be a proximiate [sic] cause of Elbert's alleged injury. *Plummer v. Lederle Laboratories*, 819 F.2d 349, 358-59 (2d Cir.), *cert. denied*, 484 U.S. 898 (1987). Even if Dr. Richardson were not aware of the risk of bone loss due to synovitis, no evidence was introduced to indicate that Elbert's treatment would have been different during the relevant period or that the implant would have been removed; as of February, 1990, according to Dr. Richardson's testimony, Elbert's knee prosthesis was "working perfectly." (Tr. 8/3/93 at 165.)

Although the finding of negligence is normally within the province of the trier of fact, where the facts are such that an ordinary person would not have personal knowledge from which to judge whether the conduct complained of was in breach of duty, or the causation of the injury, expert evidence is required to prove negligence. *Compare Brown v. Clark Equipment Co.*, 62 Haw. 530, 537 (1980) (expert testimony not required where the issues were within the common knowledge of jurors, issue of negligence in design of construction vehicle with blind spot, without mirrors or without advising purchasers that mirrors available for installation); *Cozine v. Hawaiian Catamaran, Ltd.*, 49 Haw. 77, 83, 412 P.2d 669, 676 (1966) ("It requires no expert testimony to enable a jury to infer that in the ordinary course of event [sic] and if due care is used the mast of an excursion boat does not snap off. . . . "). Expert testimony is routinely required to establish the standard of care in professional malpractice cases, save for those factual circumstances which fall within the ordinary understanding of jurors. W. Page Keeton, et al., Prosser and Keeton on the Law of Torts, § 32 at 189 (5th ed. 1984) ("Where the matter is regarded as within the common knowledge of laymen, as where a surgeon saws off the wrong leg, or there is injury to a part of the body not within the operative field, it has been held that the jury may infer negligence without the aid of any expert.")

The jury was instructed that the duty of care a manufacturer owes a user "is dependent upon the foreseeable risk of harm to potential users in light of then current scientific or medical knowledge and discoveries." (Jury Instruction No. 23.) Without Kayser's testimony, there

was no expert testimony to establish the standard of "then current scientific or medical knowledge and discoveries," whether Howmedica breached its duty as a manufacturer by failing to meet its duty, or, indeed, whether a failure by Howmedica to use ordinary care was the cause of Elbert's injuries. It is not the case here that a prosthetic knee will not fail absent a defect. Indeed, the jury explicitly found that Elbert was partially at fault for the failure of his knee.

Elbert's reliance upon Drs. Richardson and Lyons, Cook and Stark, as effective support of the jury's verdict for negligence is ill founded. Certainly these witnesses, taken together, did support Plaintiff's contention that the PCA knee failed sooner than expected, that there existed certain concerns that the polyethylene was the "weak link" in the device, that the design of the PCA knee had certain drawbacks. However, this evidence fails to establish the relevant standard of care or show that Howmedica breached their duty.

This court finds that the design, manufacture, testing, and development of replacement knee prostheses products is well beyond the knowledge of the lay juror; what function is to be achieved, by what methods, and at what relative risk cannot be said to be within the understanding of the individuals selected for the jury pool. Furthermore, as said by the Ninth Circuit, the PCA knee was "unavoidably imperfect, as are all man-made joints." Mem. Op. at 4. That being the case, this court holds that expert testimony is required to establish the relevant standard of care for reasonably prudent manufacturer of knee prostheses in order for the jury to determine if it was breached, as well as determine if any such breach

caused Elbert's injuries. The absence of such testimony after remand requires that the court enter judgment in favor of Defendant on Plaintiff's claim for negligence.

In ruling on Defendant's motion for judgment as a matter of law at trial, this court explained that:

> Now, on the negligence issues, this is a closer call in my judgment. But I think Mr. Kayser's testimony, also, in my view, creates a jury issue as to negligent manufacturing processes. . . . [H]is testimony concerning how he thought the practices of defendant in this case varied from those standard practices that he is aware of does, in my view, create a jury issue.

(Tr. 8/10/93 at 662.) Whereas Kayser's testimony is no longer part of this case, this court now concludes that the remaining evidence does not give rise to a jury issue in negligence. Rather, loss of Kayser's testimony is fatal to Plaintiff's negligence claim.

ii. Breach of Implied Warranty

Under Hawaii law, the Plaintiff in product liability action for breach of implied warranty for personal injury is required to show that the product was "unmerchantable sufficient to avoid summary judgment on the issue of defectiveness in a tort strict products liability suit." *Larsen v. Pacesetter Systems, Inc.*, 74 Haw. 17, 22 (1992). In accordance with such standard, the jury was instructed that in order to find for Plaintiff on a breach of implied warranty theory, Plaintiff had to prove by a preponderance of the evidence that "[P]laintiff's knee prosthesis was not fit for the ordinary purposes for which knee

prostheses are used. . . . " (Jury Instruction No. 33.) Whereas the only evidence that the PCA knee was not fit for the ordinary purposes for which it was used came from Kayser, Plaintiff has a fatal defect of his proof of a breach of implied warranty. Despite Dr. Richardson's testimony that he believed the knee should have lasted longer, and Dr. Bloebaum's testimony that there were tests which were possible to have been administered, no competent expert evidence remains in Plaintiff's case from which the jury could have concluded that the PCA knee device was not fit for ordinary purposes as a knee prosthesis. The evidence which does remain is that the PCA knee functioned well for Elbert for a period of years and that Elbert himself "pushed his joint beyond its mechanical endurance." Mem. Op. at 4.

Whereas Kayser's testimony is no longer part of this case, this court concludes that the remaining evidence does not give rise to a jury issue in breach of implied warranty.

CONCLUSION

This court finds that absent Kayser's testimony, there was insufficient evidence of negligence or breach of implied warranty by Howmedica to support the jury verdict returned in favor of Plaintiff. Absent such evidence, this court must rule in Howmedica's favor, as a matter of law, on Plaintiff's claims for negligence and breach of implied warranty.

For the reasons stated above, the court GRANTS Defendant's Motion for Disposition of Case Upon Remand and DENIES Plaintiff's Motion for New Trial. It

is ORDERED that judgment be entered in Defendant's favor on Plaintiff's remaining causes of action.

IT IS SO ORDERED.

Dated: Honolulu, Hawaii, June 21, 1996.

/s/ Barry M. Kurren
Barry M. Kurren
United States
Magistrate Judge

NOT FOR PUBLICATION
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

GEORGE ELBERT, Plaintiff-Appellant, vs. HOWMEDICA, INC., a Division of PFIZER HOSPITAL PRODUCTS GROUP, INC., Defendant-Appellee.	No. 94-15683 D.C. No. CV-91-00616-HMK MEMORANDUM* (Filed Jun. 28, 1995)

Appeal from the United States District Court
for the District of Hawaii
Barry M. Kurren, Magistrate Judge, Presiding

Argued and Submitted May 3, 1995
Honolulu, Hawaii

Before: PREGERSON, KOZINSKI, and HAWKINS, Circuit Judges.

Following a jury verdict, the district court entered judgment of $196,775 for George Elbert against Howmedica, Inc. for damages caused by an allegedly defective prosthetic knee ("PCA knee") manufactured by Howmedica. We have jurisdiction under 28 U.S.C. § 1332 and 28 U.S.C. § 1291.

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*This disposition is not appropriate for publication and may not be cited to or by the courts of this circuit except as provided by 9th Cir. R. 36-3.

We affirm the decisions denying preemption, reconciling the jury's verdicts and protecting Howmedica's confidential documents.

We conclude that the court erred in admitting certain expert testimony, and on that basis we reverse and remand.

The jury found that Howmedica was negligent and breached an implied warranty in its manufacture and sale of the PCA knee. But the jury found no strict liability.

Howmedica appeals the district court's verdict on three grounds: (1) the district court erred in admitting Kenneth Kayser's testimony regarding the PCA knee deterioration (delamination) and Howmedica's breach of due care in the manufacture and testing of the PCA knee; (2) Elbert's state law claims alleging negligence and breach of implied warranty were preempted by the Medical Device Amendments ("MDA") to the Food and Drug Administration regulations; and (3) the jury's findings of negligence and breach of implied warranty are not reconcilable with its finding against strict liability.

Elbert appeals the district court's denial of his motion to lift the pre-trial stipulated order protecting Howmedica's confidential documents. Elbert does not appeal the finding of no strict liability. The issue of strict liability, therefore, is not before the Court.

I

Elbert's expert in this case, Kenneth Kayser, was an electrical engineer who admitted to having no training or

familiarity with prosthetic knee joints or their components prior to his enlistment as an expert witness. Having never before seen a PCA knee, Kayser drew his conclusions regarding Howmedica's manufacturing process and duty to test only from reviewing extracts of articles others had published. Kayser presented no evidence of his experience or qualifications regarding the specific subject areas in which he offered testimony. Yet Kayser's testimony was crucial to the issue of delamination, the critical flaw alleged in the PCA knee. Kayser was the only witness who offered testimony asserting that Howmedica could have known and should have known its PCA knee would delaminate and thereby produce Elbert's injury.

The jury's award against Howmedica for negligence and breach of warranty, despite its finding of no strict liability, is strong evidence that Kayser's testimony was prejudicial. We find that the district court abused its discretion under Fed. R. Evid. 702 in permitting the jury to hear Kayser's opinions as to subject areas which were unequivocally outside any area of expertise he might have.

Accordingly, we reverse the district court's admission of Kayser's expert testimony.

II

The district court properly considered the scope of the MDA's preemption clause in determining that Elbert's state law claims were not preempted by the MDA. 21 U.S.C. § 360k. The FDA clarified the MDA's preemption clause in its regulations: "State or local requirements are preempted only when the Food and Drug Administration

has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act." 21 C.F.R. § 808.1(d) (1992). The FDA did not establish specific standards or requirements as to the class II device PCA knee implanted into Elbert with *bone cement* in 1986. *See* 21 C.F.R. § 888.3560. Thus we affirm the district court's finding that neither the MDA nor FDA regulations preempted Elbert's state tort actions.

III

The jury's verdicts were neither unreasonable nor irreconcilable. Negligent failure to warn and breach of implied warranty are causes of action distinct from an action for strict product liability.

The jury had a number of reasons to not find Howmedica strictly liable for the PCA knee failure. First, Howmedica's product was not abnormally hazardous, since it functioned well for Elbert over a period of years. Second, the PCA knee was unavoidably imperfect, as are all man-made joints. Third, the need for the PCA knee replacement outweighed the harm from the replacement's failure. Finally, Mr. Elbert was held to be partially at fault for pushing his joint beyond its mechanical endurance.

IV

Howmedica reasonably relied on the integrity of the court's protective order when it disclosed information under the initial discovery agreements. The district court did not abuse its discretion in refusing Elbert's request to

modify a stipulated protective order for the apparent purpose of facilitating future actions against Howmedica.

We affirm the district court's denial of Elbert's motion to lift the protective order.

V

The judgment of the district court is AFFIRMED in part and REVERSED in part. We remand this case for further proceedings consistent with the views set forth above.

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NO. 96-16249
CT/AG#: CV-91-00616-BMK

GEORGE ELBERT

Plaintiff-Appellant

v.

HOWMEDICA, INC., a Division of Pfizer Hospital Products Group, Inc.

Defendant-Appellee

JUDGMENT

(Filed Jun. 3, 1998)

APPEAL FROM the United States District Court for the District of Hawaii (Honolulu).

THIS CAUSE came on to be heard on the Transcript of the Record from the United States District Court for the District of Hawaii (Honolulu) and was duly submitted.

ON CONSIDERATION WHEREOF, It is now here ordered and adjudged by this Court, that the judgment of the said District Court in this cause be, and hereby is reversed and remanded.

Filed and entered: May 8, 1998
